

FORM PTO-1390 (Modified) U.S. PATENT AND TRADEMARK OFFICE; U.S. DEPARTMENT OF COMMERCE  
(REV. 7-2005)

ATTORNEY'S DOCKET NUMBER

PB60333USw

**TRANSMITTAL LETTER TO THE UNITED STATES  
DESIGNATED/ELECTED OFFICE (DO/EO/US)  
CONCERNING A SUBMISSION UNDER 35 U.S.C. 371**

U.S. APPLICATION NO. (If known, see 37 CFR 1.5)

**10/564148**INTERNATIONAL APPLICATION NO.  
PCT/EP2004/007667INTERNATIONAL FILING DATE  
July 8, 2004PRIORITY DATE CLAIMED  
July 10, 2003

TITLE OF INVENTION

PHARMACEUTICAL FORMULATION COMPRISING LEVOTHYROXINE SODIUM

APPLICANT(S) FOR DO/EO/US

Malgorzata KONIECZNA, Heiner KROHN, Wanda ROMAN, Hendrik SCHLEHAHN, and Malgorzata Anna STROZYK

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a submission under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a submission under 35 U.S.C. 371.
3. ☒ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (24) indicated below.
4. ☒ The US has been elected (Article 31).
5. ☒ A copy of the International Application as filed (35 U.S.C. 371 (c)(2))
  - a. ☐ is attached hereto (required only if not communicated by the International Bureau).
  - b. ☒ has been communicated by the International Bureau.
  - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
  - a. ☐ is attached hereto.
  - b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3))
  - a. ☐ are attached hereto (required only if not communicated by the International Bureau).
  - b. ☐ have been communicated by the International Bureau.
  - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
  - d. ☒ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☐ An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)).
10. ☐ An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)).
11. ☐ A copy of the International Preliminary Examination Report (PCT/IPEA/409).
12. ☒ A copy of the International Search Report (PCT/ISA/210).

Items 13 to 23 below concern document(s) or information included:

13. ☒ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
14. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
15. ☒ A **FIRST** preliminary amendment.
16. ☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
17. ☐ A substitute specification.
18. ☐ A power of attorney and/or change of address letter.
19. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 - 1.825.
20. ☐ A second copy of the published International Application under 35 U.S.C. 154(d)(4).
21. ☐ A second copy of the English language translation of the International Application under 35 U.S.C. 154(d)(4).
22. ☒ Express Mail Label No. EV332065902US

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

U.S. APPLICATION NO. (if known, see 37 CFR 1.5) <div style="font-size: 24pt; font-weight: bold; text-align: center;">10/564148</div>	INTERNATIONAL APPLICATION NO. <div style="font-weight: bold; text-align: center;">PCT/EP2004/007667</div>	ATTORNEY'S DOCKET NUMBER <div style="font-weight: bold; text-align: center;">PB60333USw</div>												
23. Other items or information: Copy of PCT publication coverage Copy of PCT Request An unexecuted Declaration														
The following fees have been submitted:		CALCULATIONS    PTO USE												
24. <input checked="" type="checkbox"/> Basic national fee ..... \$300	\$	\$300.00												
25. <input checked="" type="checkbox"/> Examination fee (37 CFR 1.492(c)) If the written opinion prepared by ISA/US or the International preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article ..... \$0 All other situations. .... \$200	\$	\$200.00												
26. <input checked="" type="checkbox"/> Search fee (37 CFR 1.492(b)) If the written opinion of the ISA/US or the International preliminary examination report by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4). . . \$0 Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the as an International Searching Authority. .... \$100 International Search Report prepared by an ISA other than the US and provided to the previously communicated to the US by the IB. .... \$400 All other situations. .... \$500	\$	\$400.00												
<b>TOTAL OF 24, 25 and 26 =</b>		\$ 900.00												
<input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(j)). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.														
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20%;">Total Sheets</td> <td style="width: 20%;">Extra Sheets</td> <td style="width: 40%;">Number of each additional 50 or fraction thereof (round up to a whole)</td> <td style="width: 20%;">RATE</td> </tr> <tr> <td style="text-align: center;">13 - 100 =</td> <td style="text-align: center;">0 /50 =</td> <td style="text-align: center;">0</td> <td style="text-align: center;">x \$250.00</td> </tr> </table>	Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round up to a whole)	RATE	13 - 100 =	0 /50 =	0	x \$250.00	\$	\$0.00				
Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round up to a whole)	RATE											
13 - 100 =	0 /50 =	0	x \$250.00											
Surcharge of \$130.00 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)).			\$											
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20%;">CLAIMS</td> <td style="width: 20%;">NUMBER FILED</td> <td style="width: 40%;">NUMBER EXTRA</td> <td style="width: 20%;">RATE</td> </tr> <tr> <td>Total claims</td> <td style="text-align: center;">14 - 20 =</td> <td style="text-align: center;">0</td> <td style="text-align: center;">x \$50.00</td> </tr> <tr> <td>Independent claims</td> <td style="text-align: center;">1 - 3 =</td> <td style="text-align: center;">0</td> <td style="text-align: center;">x \$200.00</td> </tr> </table>	CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	Total claims	14 - 20 =	0	x \$50.00	Independent claims	1 - 3 =	0	x \$200.00	\$	\$0.00
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE											
Total claims	14 - 20 =	0	x \$50.00											
Independent claims	1 - 3 =	0	x \$200.00											
MULTIPLE DEPENDENT CLAIMS (if applicable) <input type="checkbox"/> + \$360.00		\$ 0.00												
<b>TOTAL OF ABOVE CALCULATIONS =</b>		\$ 900.00												
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2.			\$ 0.00											
<b>SUBTOTAL =</b>		\$ 900.00												
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).			\$ 0.00											
<b>TOTAL NATIONAL FEE =</b>		\$ 900.00												
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40 per property +			\$ 0.00											
<b>TOTAL FEES ENCLOSED =</b>		\$ 900.00												
Amount to be		\$												
Amount to be		\$												

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

- a. ☐ A check in the amount of \$ \_\_\_\_\_ to cover the above fees is enclosed.
- b. ☒ Please charge my Deposit Account No. 07-1392 in the amount of \$ \$900.00 to cover the above fees.  
A duplicate copy of this sheet is enclosed.
- c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 07-1392. A duplicate copy of this sheet is enclosed.
- d. ☐ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

**NOTE:** Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.

SEND ALL CORRESPONDENCE TO:

CUSTOMER NO. 23347

Bonnie L. Deppenbrock  
SIGNATURE

Bonnie L. Deppenbrock  
NAME

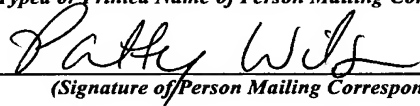
NAME

28,209  
REGISTRATION NUMBER

REGISTRATION NUMBER

1/6/2006  
DATE

DATE

<b>CERTIFICATE OF MAILING BY "EXPRESS MAIL" (37 CFR 1.10)</b> Applicant(s): <b>Konieczna et al.</b>			Docket No. <b>PB60333USw</b>	
Application No.	Filing Date	Examiner	Customer No. 23347	Group Art Unit
Invention: <b>PHARMACEUTICAL FORMULATION COMPRISING LEVOTHYROXINE SODIUM</b>				
<p>I hereby certify that the following correspondence:</p> <div style="border: 1px solid black; padding: 5px; margin: 10px 0;"><b>Submission under 35 USC 371 including a Preliminary Amendment, ISR and Written Opinion, IDS-1449, copies of 2 references, an unexecuted Declaration, copy of PCT publication coverage, and a copy of PCT Request.</b></div> <p style="text-align: center;"><i>(Identify type of correspondence)</i></p> <p>is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on</p> <p style="text-align: center;"><u>1/10/2006</u> (Date)</p> <div style="text-align: center; margin-top: 20px;"><u>Patty Wilson</u> (Typed or Printed Name of Person Mailing Correspondence)  (Signature of Person Mailing Correspondence) <u>EV332065902US</u> (Express Mail Mailing Label Number)</div>				
<b>Note: Each paper must have its own certificate of mailing.</b>				